

## Remarks/Arguments

This application has been carefully considered in view of the Initial Office Action on the merits mailed October 18, 2005. As a result, amendments have  
5 been made to the Abstract, Specification and the Claims in an effort to place the application in condition for formal allowance.

Claims 1-10 have been rejected under 35 U.S.C. 103(a) as being obvious and therefore not patentable over the references to EP 982236 to Nicolais when considered in view of the teachings of EP 737481 to Hamilton et al and US  
10 5881534 to Ahlqvist. For the reasons set forth below, reconsideration and withdrawal of this grounds for rejection is requested and favorable consideration and allowance of the claims solicited.

The Examiner is correct in stating that the reference to Nicolais discloses a process wherein an implant is placed in a gas impermeable sachet under  
15 vacuum and sealed within the sachet and further that the sealed sachet is placed within an outer envelope and that the envelope is sealed and that the implant is thereafter sterilized by irradiation. What the reference does not suggest nor teach is the formation or creation of an inert gaseous atmosphere within the envelope in which the sachet is sealed. The Examiner has taken a position that it  
20 would be obvious to create an inert atmosphere within the envelope based upon the teachings of the reference to Ahlqvist. It is respectfully submitted, however, that neither the reference to Nicolais or Ahlqvist teach or suggest the method of the present invention nor would one of ordinary skill in the art look to modify the process of Nicolais to create or establish an inert gas within the outer  
25 envelope for the purposes discussed in the present application.

The present invention is an improvement over the teachings of the prior art in that the present invention prevents ambient air, particularly oxygen, from

coming into contact with a polyethylene implant even if the integrity of an inner sachet, in which the implant is sealed, is compromised such that the sachet is no longer truly sealed, see the discussion beginning at line 19 of page 2 and at line 16 of page 7 of the present application. Also, as set forth beginning at line 16 of page 7, the inert gas within the outer envelope provides a function of shock absorption for the implant during transportation. An additional feature of the invention not disclosed by the prior art and as claimed in claim 6 is that the envelope, when it is returned to atmospheric pressure, has a more balanced internal to exterior pressure differential that reinforces the integrity of the envelope.

The reference to Ahlqvist teaches a sterilization process wherein a polymeric material is enclosed in a gas impermeable package together with an oxygen absorber in order to prevent the polymeric material from being damaged by free radicals formed with oxygen during irradiation of the material within the package. Further, at column 5, beginning at line 26 of the reference, it is specifically stated that it is purpose of the teachings of the reference to “obtain a safe and reproducible sterilization of sensitive medical objects without being dependent on expensive methods like evacuating air and introducing inert gases and steam sterilisation.”

The Examiner references the discussion in the reference that includes lines 48-52 of column 6, however, the next sentence of the reference clearly demonstrates that the reference does not contemplate filing an outer envelope with an inert gas, as it states “An important advantage of the invention is the possibility of sealing the gas impermeable package in air, without the use of inert gases, and still be able to obtain an advantageous  $\gamma$ -radiation sterilization without side reactions.”

In view of the foregoing, the reference to Ahlqvist et al does not suggest to one of ordinary skill in the art of sterilization and packaging and shipping of implants that an implant contained within an inner sachet that has been subjected to an internal vacuum should be protected from being damaged to prevent ambient air or oxygen from contaminating the enclosed implant by sealing the sachet in an outer envelope filled with an inert gas. The reference to Ahlqvist teaches away from the use of vacuum environments and expensive inert gases. It is respectfully submitted that, not only does the reference not teach or suggest an inert gas filled envelope, but the reference is such as to direct one of ordinary skill in the art to avoid the use of inert gas and in vacuum environments for sterilization of medical items.

As neither the primary or the secondary references discussed above recognize the desire to provide an outer envelope filled with an inert gas to provide a safety barrier to protect an implant should the inner sachet be compromised or leak, as well as to provide a protective cushion for the implant and sachet during shipment, it is not believed that they can be modified to teach the characterizing elements of the present invention set forth above that clearly distinguish the present invention over the art.

The secondary reference to Hamilton et al has been considered but is not believed to teach any of the benefits of the present invention that distinguish the invention over the previously discussed references. There is no suggestion of, nor has the Examiner cited this reference with respect to, an outer envelope that is filled with inert gas. Thus even if the teachings of this reference are combined with the teachings of the other references, the combination would not teach or anticipate the claims which define the present invention.

Should the Examiner have any questions regarding this response or the amendments submitted here with or the allowability of the claims over the prior

As this response is being filed after the shortened statutory period, a request for a one month extension of time until February 18, 2006, and the required fees are submitted herewith. Any deficiencies in the fees for the extension may be charged to Deposit Account 04-1577.

~~Respectfully Submitted;~~

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